

SPECIFICATION:

Please replace pages 2-3 of the specification with following new amendment to the specification. The new amendment to the specification is shown in pages 3-5 of this preliminary amendment.

--It is well appreciated in the emu oil industry that the anti-inflammatory efficacy of different preparations of emu oil varies significantly. This variation can be so significant that it hampers the therapeutic use of this oil (6) and hence its commercial value. At the moment, no standard protocols are followed in the farming or source of emu, the part of the bird from which the oil is obtained, the method of preparation or storage of emu oil (7). In fact, there are conflicting data on the therapeutic efficacy of different emu and other oils and there appear to be at least two reasons for this.

Firstly, most animal fats and oils are complex mixtures with highly variable chemical compositions. The individual components almost certainly have different effects on immune function and may, in addition, inhibit the activities of other components or even synergise with each other.

Secondly, the immune system is made up of a number of different cell types, each with highly specific roles and not all of which respond in the same way to fats and oils. Optimum activity of an oil is therefore dependent on the condition being treated, as the cell types each have defined roles.

Furthermore, current scientific assays and tests on the efficacy of oils have presented conflicting results. The inability to quality control and standardise the oil for anti-inflammatory properties has posed a major limitation to the use of emu oil as a therapeutic agent. Variations in these factors can, in part, contribute to variations in the efficacy of the oil and have prevented its use in humans as a pharmaceutical agent, more

particularly as a treatment for inflammatory diseases, conditions or responses.

In particular, oils with potential therapeutic activity can be claimed to be active, but there is currently no way of distinguishing between or comparing their actual levels of anti-inflammatory activity.

An accurate assessment of the immunosuppressive activity prior to therapeutic use would greatly increase the consistency and reproducibility of treatment with a particular oil, as well as providing a means of increasing its therapeutic activity.

Unfortunately, the prior art is lacking in methods of assessing the likely therapeutic activity of an oil sample.

The present inventor has developed a method of measuring the intrinsic capacity of an oil to suppress the immune system of humans and animals. The method also allows the testing of the level of therapeutic activity of an oil, thereby enabling differentiation between oil samples of low and high therapeutic activity, and enabling oils to be graded for their therapeutic activity.

SUMMARY OF THE INVENTION

According to one aspect, the present invention overcomes or reduces at least some of the above-mentioned problems by providing a novel scientific approach to accurately determine whether a compound has anti-inflammatory activity. In particular, the novel assays allow the screening of compounds for the purposes of prophylactic and therapeutic use in treating or ameliorating the symptoms of T-cell, macrophage or neutrophil mediated diseases in mammals.

The present inventor has found that, if samples of different oils with potential anti-inflammatory activity are serially diluted and tested at each level of dilution for their anti-inflammatory activity using an *in vivo* or *in vitro* test, the oils can be graded according to

the concentration of the oil, or level of dilution, that causes equivalent anti-inflammatory activity in the *in vivo* or *in vitro* test. Thus, it is possible, using the serial dilution approach, to determine levels of dilution/concentration where each oil demonstrates, for example, 25% inhibition or 50% inhibition of an inflammatory marker in the *in vivo* or *in vitro* test. In this manner, different levels of anti-inflammatory activity can be scientifically attributed to oils having potential anti-inflammatory therapeutic activity. The oil which, at the greater dilution (lower concentration), provides a specified percentage inhibition of an inflammatory marker has the greater potential anti-inflammatory therapeutic effect.

In particular, the invention is based on the measurement of the capacity of an oil or fat, alcoholic extracts of an oil or fat, biologically active components of an oil or a fat, or preparations comprising oils or fats, to suppress the activity of T-cells, macrophages or neutrophils in humans or animals in response to chemical and/or biological agents that activate these cell types. Measurements are made either in mice (ie *in vivo*) or in human T-cells, macrophages or neutrophils isolated from blood. The method can be used to quantify the total T-cell, macrophage and/or neutrophil suppressive activities per unit mass or volume in any oil or fat and the degree of suppression of T-cell, macrophage or neutrophil responses by an oil or fat.

Using a model representative of a *chronic* inflammatory reaction (the delayed type hypersensitivity (DTH) reaction), emu oil was found to inhibit T lymphocytes and macrophage recruitment to the site of inflammation. --